#### Home Use of Medical Devices

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## A Buffet of Methods regarding Home Use of Devices

- A taste of some approaches with examples
- Goal: Influence the menu plan and recipes determined by CDRH in future

#### Roadmap

- Why the VA is interested
- Devices used in VA population outside hospital
- Healthcare Failure Modes and Effects Analysis (HFMEA) Scoring Matrix
- Define the expected user of a given Medical Device
- Matching technology to the patient
- Design it right
- How can the culture of device design be explicitly changed?

#### Why the VA is interested

- Within the VA, over 6 million enrolled Veterans Nationwide
- \$23 billion in healthcare resources<sup>1</sup>
- Complex care issues, elderly population
- Harm resulting from use injuries degrades care and is costly
- Home Based Care can save resources<sup>2</sup>

# Devices Used in VA Population at Home<sup>2,3</sup>

- Ambulation and bath aides
- Oxygen services
- Life-sustaining and/or custom electrical equipment
- Intravenous pumps
- Diagnostic devices
- Telemedicine technology

# HFMEA<sup>TM--</sup> Prospective Ranking of Severity and Frequency

- "Healthcare Failure Modes and Effects Analysis" = prospective risk assessment
- Determine the Severity and Probability of each potential cause.
- This will lead you to the Hazard Matrix Score.
- The Hazard Matrix Score ranks devices for proceeding with the HFMEA
- For more about HFMEA<sup>TM</sup>

www.patientsafety.gov

## HFMEA<sup>TM</sup>-- Severity

#### **Catastrophic Event**

(Traditional FMEA Rating of 10 - Failure could cause death or injury)

<u>Patient Outcome</u>: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, Surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family

<u>Visitor Outcome:</u> Death; **or** hospitalization of 3 or more.

**Staff Outcome:** \* A death or hospitalization of 3 or more staff

**Equipment or facility:** \*\*Damage equal to or more than \$250,000

**<u>Fire</u>**: Any fire that grows larger than an incipient

#### **Major Event**

(Traditional FMEA Rating of 7 – Failure causes a high degree of customer dissatisfaction.)

<u>Patient Outcome</u>:Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients

<u>Visitor Outcome</u>: Hospitalization of 1 or 2 visitors <u>Staff Outcome</u>: Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty injuries or illnesses

**Equipment or facility:** \*\*Damage equal to or more than \$100,000

<u>Fire:</u> Not Applicable – See Moderate and Catastrophic

## HFMEA<sup>TM</sup>-- Severity

#### **Moderate Event**

(Traditional FMEA Rating of "4" – Failure can be overcome with modifications to the process or product, but there is minor performance loss.)

<u>Patient Outcome:</u> Increased length of stay or increased level of care for 1 or 2 patients

<u>Visitor Outcome:</u> Evaluation **and** treatment for 1 or 2 visitors (less than hospitalization)

<u>Staff Outcome:</u> Medical expenses, lost time or restricted duty injuries or illness for 1 or 2 staff

**Equipment or facility:** \*\*Damage more than \$10,000 but less than \$100,000

Fire: Incipient stage‡ or smaller

#### **Minor Event**

(Traditional FMEA Rating of "1" – Failure would not be noticeable to the customer and would not affect delivery of the service or product.)

<u>Patients Outcome:</u> No injury, nor increased length of stay nor increased level of care

<u>Visitor Outcome:</u> Evaluated and no treatment required **or** refused treatment

**<u>Staff Outcome:</u>** First aid treatment only with no lost time, nor restricted duty injuries nor illnesses

**Equipment or facility:** \*\*Damage less than \$10,000 or loss of any utility\* without adverse patient outcome (e.g. power, natural gas, electricity, water, communications, transport, heat/air conditioning).

<u>Fire:</u> Not Applicable – See Moderate and Catastrophic

#### HFMEA<sup>TM</sup>— Probability Rating

- Probability Rating
  - Frequent Likely to occur immediately or within a short period (may happen several times in one year)
  - ❖Occasional Probably will occur (may happen several times in 1 to 2 years)
  - ❖Uncommon Possible to occur (may happen sometime in 2 to 5 years)
  - ❖Remote Unlikely to occur (may happen sometime in 5 to 30 years)

# HFMEA<sup>TM</sup>– Hazard Scoring Matrix

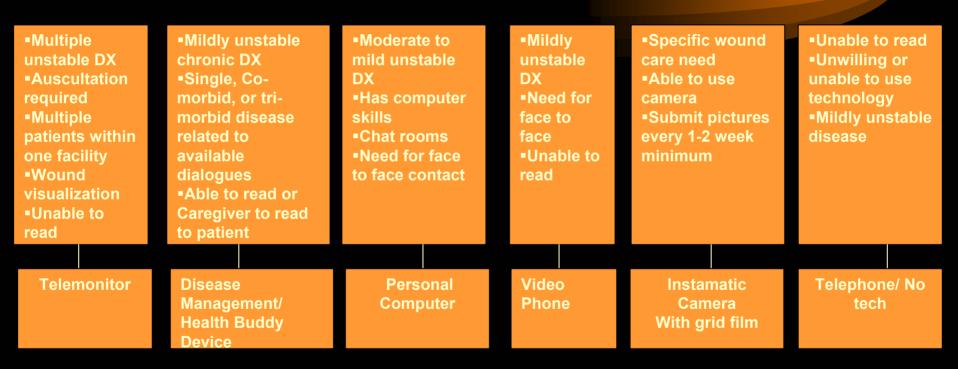
	Severity				
Probability		Catastrophic	Major	Moderate	Minor
	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

#### Define the expected user of a given Medical Device

- IV Pump
  - Visiting Nurse
  - LPN or RN
  - Reasonable to think it will be used by a clinician
- Ventilator
  - Vendor
  - Reasonable to think it will be used by an expert

- Blood Pressure Cuff or Lifting Device
  - Client
  - Client family member or friend
  - Reasonable to think it will be used by someone other than an "expert"

#### Matching technology to the patient -- North Florida/South Georgia VISN 8<sup>3</sup>



"Many advances in technology are needed, but none are more important than a concentrated focus on hardware usability by patients."<sup>4</sup>

#### Design it right

- Develop requirements and device designs based on the actual users of the devices
  - "Diseases can cause cognitive or physical limitations that make barely usable systems unusable."5
  - Recipients of home-based care are empowered by participating in the development of devices
  - Actual users
  - Actual environment of use
  - Actual user tasks start to finish

## Design it right

- If actual users and environment cannot be used:
  - Simulate physical challenges of users
  - Simulate the environment of use

## Design it right

- Oxygen use
  - User question is: how much time do I have left in this O<sub>2</sub> tank?
  - Not PSI or gauge readings translate to answer their question
- Mail Order Pharmacy
  - No "human" in the loop at point of delivery
    - to point out label info
    - talk about fine points of administration
    - answer questions

# How can the culture of device design be explicitly changed? (User-centered aspects)

- Mentor medical device manufacturers on shifting focus to robust pre- and post-market user-centered design
  - Mentoring Approach: Breakthrough sessions work at White River Junction Patient Safety Center of Inquiry (now part of VA NCPS)
  - Strategic user-centered design "management consulting"
- How to Implement?
  - Internal resource at CDRH?
  - Contract resource outside CDRH?

#### Website for VA National Center for Patient Safety

www.patientsafety.gov

#### References

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